UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/744,748	01/29/2001	Hisashi Narimatsu	1241.17	4282

7590 01/05/2007

Fitzpatrick Cella Harper & Scinto
30 Rockefeller Plaza
New York, NY 10112-3801

EXAMINER	
RAO, MANJUNATH N	
ART UNIT	PAPER NUMBER
1652	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/05/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/744,748	NARIMATSU ET AL.	
	Examiner	Art Unit	
	Manjunath Rao	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 September 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2,4-18,24 and 51-53* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *2,4-6,16-18,24,51 and 53* is/are allowed.

6)☒ Claim(s) *7-8, 12-15, 52* is/are rejected.

7)☒ Claim(s) *9-11* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 2, 4-18, 24, 51-53 are currently pending in this application.

Applicants' amendments and arguments filed on 9-22-06 and 9-12-06, have been fully considered and are deemed to be persuasive to overcome the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. Specifically, Examiner has withdrawn the previous rejections under 35 USC 112, 1st and 2nd paragraphs in view of claim amendments.

Amendments to Specification

Examiner acknowledges the amendment filed on 9-22-06, in which applicants state as follows.

> **Sir:**
>
> **It has come to the attention of the undersigned that the verified translation of Applicants' priority document JP 10-213823 filed herein on April 16, 2004 inadvertently contained copies of Figures 1-16 of record in the pending US application. However, this was incorrect; only Figures 1-7 are referred to in JP 10-213823. (See the verified specification at page 77, line 15 (Figure 1), page 78, line 4 (Figure 2), page 78, line 9 (Figure 3), page 86, line 11 (Figure 4), page 89, line 23 (Figure 5), page 91, line 18 (Figure 6) and page 96, line 13 (Figure 7).) Figures 8-16 are not discussed in that document.**
>
> **Accordingly, to complete the record, enclosed are replacement sheets of Figures 1-7 which should be appended to the verified translation.**

This is highly unclear to the Examiner. The English translation document already has figures 1-7. Therefore, it is not clear as to what purpose would be served by appending another

set of figures 1-7 to that document. On the contrary it is the Examiner's understanding that if figures 8-16 are not discussed in that document, those figures must be removed from that document. In view of this confusion the above amendment has not been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 7-8, 12-15, 52 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an enzyme with SEQ ID NO:1 or 2 having the activity of transferring fucose to an N-acetylglucosamine structure in an N-acetyllactosamine structure existing in a nonreducing terminus of a sugar chain via an alpha 1,3-linkage, but not having a similar activity to transfer fucose to N-acetylglucosamine residue in an alpha 2,3-sialyl N-acetyllactosamine structure, and the encoding polynucleotide with SEQ ID NO:3, 4, or 5, their respective full length complements, vectors comprising said polynucleotides and isolated host cells transformed with said vectors and a method of making the polypeptide using said transformed host cells does not reasonably provide enablement for any or all transgenic non-human animals or any or all plants or any or all plant cells transformed with said vectors and methods of making the polypeptide using said any or all transgenic non-human animals or any or all plants or any or all plant cells. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required, are summarized in *In re Wands* (858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)) as follows: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claim(s).

Claims 7-8, 12-15, 52 are so broad as to encompass any or all transgenic non-human animals or any or all plants or any or all plant cells transformed with vectors comprising polynucleotides encoding the polypeptide with SEQ ID NO:1 or 2 and methods of making the polypeptide using said any or all transgenic non-human animals or any or all plants or any or all plant cells. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of hosts for transformation/transfection broadly encompassed by the claims and the complex procedures of generating any or all types of transgenic plants and animals.

Since the art or the specification does not teach a single universal method for transforming or transfecting any or all types of non-human animals and any or all plants or plant cells, predictably of which method to be used with which animal or plant to obtain the desired out come, *i.e.*, expression and production of the encoded polypeptide requires a knowledge of and guidance with regard to which method can be used for which animal or plant and which animal or plant is not tolerant or tolerant to said transfection and the detailed knowledge of the ways in which known methods can be modified and used for transfection/transformation. However, in this case the disclosure is limited to the generation of transformed microorganisms

as opposed to generating transgenic animals and plants. The only support from the art regarding any genetics of animals or plants involves generating knockout animals which is exactly opposite of generating transgenics. Applicants provide no examples of methods that can be used or examples of a transgenic plant or animal which was generated by transfecting the claimed polynucleotides and show the production of the polypeptide from such transgenics.

While transformation and transfection techniques are known, it is limited to transformation of microorganisms and to only some animals. Transfection of plants is generally known to be more complicated than transfection procedures known for animals. Furthermore it is not routine in the art to screen for multiple hosts of plants and animals for making transgenics, as encompassed by the instant claims. This is because, it is well known in the art that generating transgenic plants and animals are highly complex and all such generated transgenics may not be successful in expressing said polypeptide.

The specification does not support the broad scope of the claims which encompasses making transformants and transgenics using any non-human animal, any plant or any plant cells because the specification does not establish: (A) a single universal method of transformation/transfection that can be used for successfully transforming/transfecting any non-human animal, any plant or any plant cell; (B)procedures for generating transgenic plants and animals using the claimed polynucleotide and a demonstration of the production of polypeptides from such transgenics; and (C) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope

of the claims broadly including any or all non-human animals and plants and plan cells for generation of transgenic plants and animals using said polynucleotides. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, producing transgenics as claimed and using them to make the expressed polypeptides is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See *In re Wands* 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

In response to the above rejection, applicants have traversed. Applicants argue that specification at page 3, lines 3-7 describes that "the polypeptide of the present invention can be produced in an animal having the transgene "according to a known method as described in American Journal of Clinical Nutrition, 63, 639S (1996), American Journal of Clinical Nutrition, 63,627S (1996), Bio/Technology, 9,830 (1991)". Applicants also argue that those ordinarily skilled in this art could produce transgenic animals based on common general technical knowledge at the time this invention was made and provides examples of enzymes made in transgenic mice. Examiner respectfully disagrees with such an argument. As can be seen from the publications that applicants provide in the specification as well as in their argument, all these references are limited to discussion of the method of making transgenic mice. Furthermore the reference of Alan Colman (Am. J. Clin. Nutr., Vol 63, 639S) clearly states that,

> The murine model, however, is not totally reliable because both protein yields and protein quality are greater from larger animals such as sheep (2) and pigs (3). The length of time to milk production is obviously a major factor in the choice of species. However, other considerations apply, such as the disease status of the animals, litter size, and volume of milk. The relative merits of each species according to a variety of criteria are shown in Table 2.

Therefore, it cannot be simply concluded that the claims drawn to method of making the transgenics using any or all non-human animals is fully enabled in the specification. Similarly, applicants show no support for method of making transgenic plants which is considered much more complicated than making transgenic animals because of lack of a convenient vector that can be used to transform any or all plant cells.

Applicants also argue that there is no need for them to provide examples and that they are not claiming substituted sequences, and the references discussed above all illustrate that producing transgenic animals are enabled. It appears applicants have confused the rejection since it was addressing both the variants as well as method of making transgenics. It is clear to the Examiner that in the present set of claims applicants are not claiming variants. However, they are claiming method of making the protein using transgenic animals and plants for which the specification does not provide an enabling support. Therefore the above rejection is maintained.

Conclusion

Claims 2, 4-6, 16-18, 24, 51, 53 are allowable.

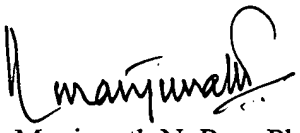
Claims 9-11 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Manjunath N. Rao, Ph.D. whose telephone number is 571-272-0939. The Examiner can normally be reached on 7.00 a.m. to 3.30 p.m. If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Ponnathapura Achutamurthy can be reached on 571-272-0928. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300 for regular communications and for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.



Manjunath N. Rao, Ph.D.
Primary Examiner
Art Unit 1652

December 22, 2006